



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) The approaches used to minimize the burden of the collection of information on those who are to respond, including the use of

appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing or request more information on the proposed project, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard, Room 5185; or call non-toll-free number (301)-443-8755; or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Population Assessment of Tobacco and Health (PATH) Study –Third Wave of Data Collection - 0925-0664-REVISION - National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925-0664, Exp. Date 9/30/2016) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the third wave of data collection. The PATH Study is a large

national longitudinal cohort study on tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The PATH Study conducts annual interviews and collects biospecimens from adults to help inform the development, implementation, and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study provides it with the capacity to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA and FDA's evaluations of associations between its regulations and tobacco use behaviors and health indicators in the population.

OMB approval is requested for 3 years. There are no capital, operating, or maintenance costs to report. There are no costs to respondents other than their time. The total estimated annualized burden hours are 53,459.

Estimated Annualized Burden Hours

Type of Respondent and Instrument	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Adults – Adult respondents at Wave 1 or Wave 2 –Extended Interview	25,692	1	1	25,692
Adults – Wave 1 youth respondents who age up to adult cohort at Wave 3 – Consent for Extended Interview	2,317	1	4/60	154
Adults – Wave 1 youth respondents who age up to adult cohort at Wave 3 – Extended Interview	1,738	1	68/60	1,970
Adults – Wave 1 youth respondents who age up to adult cohort at Wave 3 – Consent for Biological Samples	1,738	1	5/60	145

Type of Respondent and Instrument	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Adults – Biospecimen Collection: Urine	13,703	1	10/60	2,284
Adults – Biospecimen Collection: Blood	869	1	18/60	261
Adults – Tobacco Use Form	14,572	1	4/60	971
Adults – Follow-up/Tracking Participant Information Form	27,430	2	8/60	7,315
Youth – Youth respondents at Wave 1 or Wave 2 – Extended Interview	9,515	1	32/60	5,075
. Youth – Shadow youth who age up to youth cohort at Wave 3 – Assent for Extended Interview	2,420	1	3/60	121
. Youth – Shadow youth who age up to youth cohort at Wave 3 – Extended Interview	1,912	1	42/60	1,338
. Adult – Youth respondents at Wave 1 or Wave 2 – Parent Interview	9,705	1	14/60	2,265
. Adults - Parents of Shadow youth who age up to youth cohort at Wave 3 – Parent Permission and Consent for Parent Interview	2,420	1	5/60	202
. Adults - Parents of Shadow youth who age up to youth cohort at Wave 3 – Parent Interview	1,950	1	17/60	553
. Adults – Verification Interview	35,564	1	2/60	1,185
. Adults – Validation Interview	3,613	1	4/60	241
. Adults – Follow-up/Tracking Participant Information Form for Youth (completed by parents)	11,427	2	8/60	3,047
. Adults – Follow-up/Tracking Participant Information Form for sample Shadow youth (completed by parents)	2,401	2	8/60	640

Dated: February 5, 2015

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